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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,236	08/27/2003	Mark A. Dombroski	PC23251A	6195

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EXAMINER

MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,236

Applicant(s)

DOMBROSKI ET AL.

Examiner

Patricia L. Morris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 28, 29, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-27, 30 and 31 are under consideration in this application.

Claims 28, 29, 32 and 33 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

Applicant's election with traverse of Group I in the paper filed April 19, 2004 is acknowledged. The traversal is on the ground(s) that the subject matter is so interrelated that there is no burden on the examiner to search all the inventions. This is not found persuasive because for the reasons set forth in the Office action mailed March 16, 2004. The prior art of record shows that the instant compounds are well known in the art and fail to make a contribution to the prior art. Moreover, applicants have failed to advance any cogent reasons as to why the inventions are not patentably distinct.

The requirement is still deemed sound and proper and is therefore maintained.

Claims 30 and 31 have been examined to the extent readable on the elected method of use, *i.e.*, method of treating arthritis, exclusively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over al. McClure et al. (US 6,696,464).

McClure et al. generically embrace the instant compounds having the same use. Note the compounds of formula I(d) wherein R^2 represents alkyl or cycloalkyl, R^3 represents fluorine and s is 2-3, in column 21, lines 1-19.

It is believed that one having ordinary skill in the art would have found the claimed compounds prima facie obvious, since they are generically embraced by the disclosed formula; In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also In re Malagari, 499 F.2 1297, 182 USPQ 549 (CCPA 1974); In re Lemin, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960). The requisite motivation for arriving at the claimed compounds stems from the fact that they fall within the generic class of compounds disclosed by McClure et al. Accordingly, one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims, with the expectation that each of them would be suitable for the treatment of arthritis.

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It is believed well settled that a reference may be relied upon for all that it would have reasonably conveyed to one having ordinary skill in the art. In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Lamberti, 545 F.2d 747, 192 USPQ 278 (CCPA 1976); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Susi, *supra*.

Further, McClure et al. teach a compounds excluded by proviso herein. Note example 30 or compound recited in column 40, lines 41-42. The prior art compounds differ from the compounds claimed herein as alkyl homologs. The instant compound wherein R₂ is ethyl, propyl or butylare just alkyl homologs of the prior art compounds. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compound to arrive at other compounds within the claimed genus. The motivation to make these compounds is their close structural similarities to the disclosed compounds. Note that the disclosed compounds are useful for the treatment of arthritis, thus the skilled artisan would expect such structurally similar compounds to possess similar properties. While homology is considered to be present even if true "homology" is not present, such does not defeat the prima facie case of obviousness raised by the art. Attention, in this regard is directed to In re Druey et al., 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court's opinion, stated:

that in "We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants the term homologue is used by chemists at times in a broad sense, and at other times a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." 50 CCPA 1541.

Also, as the Court stated in In re Payne et al., 606 F.2d 302, 203 USPQ 245 at 255 (CCPA 1979):

"the name used to designate the relationship between related compounds is not

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necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound.”

In addition, any question of why would one conceive and use the similar compounds (i.e. “motivation”) is answered by the Court in *In re Gyrík et al.*, 596 F.2d 1012, 201 USPQ 552 at 557.

“In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties.”

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 provides for the use of the treatment of arthritis, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 31 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27, 30 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 105, 15 and 51-53 of U.S. Patent No. 6,696,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds and homologues are disclosed therein having the same use.

Conclusion

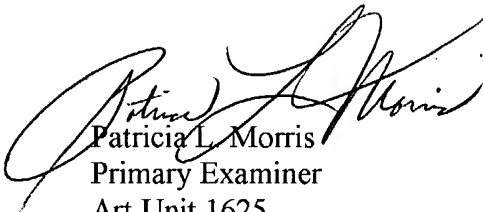
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
May 3, 2004